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DATE: February 22, 2006

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FROM: Danielle E. Leonard, Esq.

RE: PETITION TO DR. JOAN E. DENTON, DIRECTOR, OFFICE OF
ENVIRONMENTAL HEALTH HAZARD ASSESSMENT RE: LISTING OF
PERFLUOROOCTANOIC ACID ("PFOA") UNDER PROPOSITION 65

MESSAGE:

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11 Workers International Union, AFL-CIO, CLC; Sierra Club;
Environmental Law Foundation; Environmental Working
12 Group; U.S. Public Interest Research Group; Environment
California; and Natural Resources Defense Council
13

14 OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

15 UNITED STEEL, PAPER AND FORESTRY,) PETITION TO DR. JOAN E.
RUBBER, MANUFACTURING, ENERGY,) DENTON, DIRECTOR,
16 ALLIED INDUSTRIAL AND SERVICE) OFFICE OF ENVIRONMENTAL
WORKERS INTERNATIONAL UNION, AFL-) HEALTH HAZARD ASSESSMENT
17 CIO, CLC; SIERRA CLUB;) RE: LISTING OF
ENVIRONMENTAL LAW FOUNDATION;) PERFLUOROOCTANOIC ACID
18 ENVIRONMENTAL WORKING GROUP; U.S.) ("PFOA") UNDER PROPOSITION 65
PUBLIC INTEREST RESEARCH GROUP;)
19 ENVIRONMENT CALIFORNIA; and)
NATURAL RESOURCES DEFENSE)
20 COUNCIL,)

EXPEDITED CONSIDERATION
REQUESTED

21 Petitioners.
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INTRODUCTION

1. The United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC; the Sierra Club; the Environmental Law Foundation; the Environmental Working Group; the U.S. Public Interest Research Group; Environment California; and the Natural Resources Defense Council request that the Office of Environmental Health Hazard Assessment ("OEHHHA") propose perfluorooctanoic acid and its salts ("PFOA") for consideration and listing by the Carcinogen Identification Committee ("CIC") under Proposition 65 as a chemical that is "known to the state to cause cancer." California Health and Safety Code §25249.8(b); 22 C.C.R. §12305(a)(1).

2. Twenty years ago, by an overwhelming vote, the voters of California enacted Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, for a specific and overarching purpose: To enhance their protection from toxic chemicals from which slow moving government agencies had failed to provide protection. As one California appellate court put it: "Proposition 65 clearly reflects the result of public dissatisfaction with the state's efforts at protecting the people and their water supply from exposure to hazardous chemicals." *AFL-CIO v. Deukanejian*, 212 Cal.App.3d 425, 441 (1989). Proposition 65 mandates publication of a list of chemicals that cause cancer or reproductive harm – the threshold and critical step in the statutory scheme – when certain conditions are met. Only through expeditious listing could the central purpose of Proposition 65 – allowing people to be told of significant health risks and protect themselves as a matter of personal choice – be accomplished.

3. Specifically, in Proposition 65, the people stated "that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs." *Id.* at 430 (quoting preamble). To counteract the threat of hazardous chemicals, Proposition 65 declares the following rights of Californians:

"(a) To protect themselves and the water they drink against the chemicals that cause cancer, birth defects, or other reproductive harm.

1 “(b) To be informed about exposures to chemicals that cause cancer, birth defects, or other
2 reproductive harm.

3 “(c) To secure strict enforcement of the laws controlling hazardous chemicals and deter
4 actions that threaten public health and safety.

5 *Id.* at 430-31 (quoting preamble).

6 4. Those policy goals – and Proposition 65’s mandate to carry them out – remain in full.
7 force and effect. The Proposition further requires “a diligent, thorough and continuing search for
8 additional chemicals which evolving scientific knowledge demonstrates are subject to the Act.” *Id.* at
9 440. Both the scientific evidence and recent actions (and inactions) by government agencies with
10 respect to PFOA conclusively demonstrate why expedited listing of PFOA is required to carry out
11 Proposition 65’s essential purposes. More delay awaiting more studies or until some other governmental
12 entity reaches closure would represent the very result the public intended to *remedy* by enacting
13 Proposition 65 in 1986. PFOA is a highly controversial substance (1) that studies have documented
14 causes liver, pancreatic, and testicular cancer in animals; (2) that the CIC’s counterpart, the U.S.
15 Environmental Protection Agency’s Science Advisory Board, has concluded is a likely human
16 carcinogen; (3) to which there may be widespread consumer exposure to the people of California from a
17 variety of products including pots and pans; (4) the presence of which has been detected in human blood,
18 including that of children; and (5) about which there is already a heated public debate occurring about
19 the levels of cancer *risk* presented, as most recently evidenced by full page newspaper advertisements
20 denying or minimizing hazards to human health.

21 5. It is against the above background that this petition should be assessed. As discussed
22 below, as with many other chemicals listed in the past independently by the CIC and OEHHA, the
23 animal studies of PFOA show that the substance meets the requirement for listing under Proposition 65.
24 (The CIC need not even address whether the EPA’s Science Advisory Board action and other evidence
25 requires listing.) By acting quickly to list, the debate over the levels of risk presented by PFOA can take
26 place as Proposition 65 intended – with the burden of proof on the company responsible for exposure to
27 establish that the risks are insignificant and that the public right to know is unnecessary. For that process
28

1 to be prevented by government delay in the initial listing would defeat the purpose of Proposition 65 and
2 undermine the intent and confidence of California's electorate.

3 **PFOA MEETS THE REQUIREMENT FOR LISTING**
4 **UNDER PROPOSITION 65 AND APPLICABLE REGULATIONS**

5 6. PFOA must be listed under Proposition 65 if it "has been clearly shown through
6 scientifically valid testing according to generally accepted principles to cause cancer." California Health
7 and Safety Code §25249.8(b). The CIC is charged with listing such chemicals. 22 C.C.R. §12305(1).
8 In particular, under the governing regulations, a chemical is to be listed as causing cancer if "studies in
9 experimental animals indicate that there is an increased incidence of malignant tumors or combined
10 malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different
11 routes of administration or using different dose levels), or, to an unusual degree, in a single experiment
12 with regard to high incidence, site, or type of tumor, or age at onset." 22 C.C.R. §12306(e)(2).

13 7. PFOA is a synthetically-produced fluorochemical compound that is ubiquitous in modern
14 consumer and industrial products. PFOA is used to create non-stick and stain-resistant surfaces on
15 consumer products including cookware. PFOA also has numerous and varied industrial uses, in almost
16 all industry segments, including the aerospace, automotive, building/construction, chemical processing,
17 electrical and electronics, semiconductor, and textile industries.¹ PFOA is not only used in the
18 manufacture of consumer and industrial products, but can be released into the atmosphere during their
19 use, such as in the heating of non-stick cookware.² Because PFOA is not naturally occurring, all PFOA
20 in the environment is attributable to human activity.³

21 8. The EPA recently reached a settlement with DuPont that imposes the largest civil
22 administrative penalty in EPA's history, \$16.5 million, against DuPont for violations of reporting

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24 ¹ U.S. Environmental Protection Agency, "Basic Information on PFOA," available at
<http://www.epa.gov/opptintr/pfoa/pfoainfo.htm>.

25 ² Environmental Working Group, "PFCs: A Family of Chemicals That Contaminate the Planet,"
26 Part I, available at <http://www.ewg.org/reports/pfcworld/part1.php>.

27 ³ U.S. Environmental Protection Agency, "Perfluorooctanoic Acid (PFOA), Fluorinated
28 Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement,
Development, and Notice of Public Meeting," 68 Fed. Reg. 18626-01 (April 16, 2003).

1 provisions of the federal Toxic Substances Control Act and the Resource Conservation and Recovery
2 Act with respect to PFOA.⁴ The violations resolved in the settlement consist of multiple failures to
3 report information to EPA about substantial risk of injury to human health or the environment that
4 DuPont obtained about PFOA from as early as 1981 and as recently as 2004.⁵

5 9. Moreover, in 2005, the EPA issued a Draft Risk Assessment, which concludes that there
6 is evidence that PFOA is carcinogenic in animals.⁶ On February 15, 2006, EPA's Science Advisory
7 Board, which consists of non-government scientific experts drawn from academia and industry, voted to
8 approve a recommendation that the EPA increase its categorization of PFOA in the Draft Risk
9 Assessment from "suggestive evidence of carcinogenicity" to "likely to be carcinogenic" in humans.⁷
10 The EPA's Draft Risk Assessment remains in the internal review process with no estimated date for
11 finalization.

12 10. In the meantime, the EPA has asked companies to agree voluntarily to reduce their PFOA
13 releases and its presence in products by 95 percent by no later than 2010 and to work toward eliminating
14 these sources of exposure five years after that but no later than 2015.⁸ Participating companies are being
15 asked to provide their commitment to the EPA by March 1, 2006.

16 11. The stable carbon-fluorine bonds that make PFOA such a pervasive and successful
17 industrial and consumer product also result in its persistence. *There is no known environmental*
18 *breakdown mechanism for this chemical.*⁹ As a result of the chemical's stability and pervasive use, the
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20 ⁴ U.S. EPA, News Release, "EPA Settles PFOA Case Against DuPont for Largest Environmental
21 Administrative Penalty in Agency History" (December 14, 2005), available at:
<http://www.epa.gov/cgi-bin/epaprintonly.cgi>.

22 ⁵ *Id.*

23 ⁶ U.S. EPA, Draft Risk Assessment of the Potential Human Health Effects Associated With
24 Exposure to Perfluorooctanoic Acid And Its Salts, Office of Pollution Prevention and Toxics, Risk
Assessment Division (January 4, 2005), at 8.

25 ⁷ See U.S. EPA, Science Advisory Board, Draft Report (January 20, 2006), available at
http://www.epa.gov/sab/pdf/2006_0120_final_draft_pfoa_report.pdf.

26 ⁸ U.S. EPA, News Release, "EPA Seeking PFOA Reductions" (January 25, 2006), available at
27 <http://www.epa.gov/cgi-bin/epaprintonly.cgi>.

28 ⁹ Burris, J.M., Lundberg, J.K., Olsen, G., Simpson, C., and Mandel, J. 2002. Determination of

(continued...)

1 concentrations of PFOA have rapidly increased in the soil, water, and air, and in biological systems,
2 including humans and animals. Numerous studies have shown that non-occupational exposure to PFOA
3 occurs *daily*, in people of all ages, from infants to the elderly, and that the chemicals may persist in
4 human blood *for years*.¹⁰ As a result of its pervasive use in consumer and industrial products, PFOA
5 exists in the blood of the general U.S. population.¹¹ Indeed, one study found that approximately 96% of
6 the U.S. children tested had PFOA in their blood.¹² Two studies have found PFOA in donated adult
7 blood from a Los Angeles blood bank and in California's children.¹³

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12 ⁹(...continued)

13 Serum Half-Lives of Several Fluorochemicals (Interim Report No. 2), 3M Company, St. Paul, MN,
14 available at USEPA Public Docket AR-226; Corsolini, S. and Kannan, K. 2004.
15 Perfluorooctanesulfonate and related fluorochemicals in several organisms including humans from Italy.
16 Organohalogen Compounds 66:4079-4085.

17 ¹⁰ Burris (2002).

18 ¹¹ U.S. Environmental Protection Agency, "Perfluorooctanoic Acid (PFOA), Fluorinated
19 Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement,
20 Development, and Notice of Public Meeting," 68 Fed. Reg. 18626-01 (April 16, 2003). Examples of
21 studies reporting the prevalence of PFOA in human blood include the following: Olsen, G.W., Church,
22 T.R., Miller, J.P., Burris, J.M., Hansen, K.J., Lundberg, J.K., Armitage, J.M., Herron, R.M.,
23 Medhdizadehkashi, Z., Nobiletti, J.B., O'Neill, E.M., Mandel, J.H., and Zobel, L.R. 2003.
24 Perfluorooctanesulfonate and other fluorochemicals in the serum of American Red Cross adult blood
25 donors. Environ. Health Perspect. 111(16):1892-1901; Olsen, G.W., Hansen, K.J., Stevenson, L.A.,
26 Burris, J.M., and Mandel, J.H. 2003. Human donor liver and serum concentrations of
27 perfluorooctanesulfonate and other perfluorochemicals. Environ. Sci. Technol. 37: 888-891; Olsen,
28 G.W., Church, T.R., Larson, E.B., van Belle, G., Lundberg, J.K., Hansen, K.J., Burris, J.M., Mandel,
J.H., and Zobel, L.R. 2004. Serum concentrations of perfluorooctanesulfonate and other
fluorochemicals in an elderly population from Seattle, Washington. Chemosphere 54:1599-1611;
Olsen, G.W., Church, T.R., Hansen, K.J., Burris, J.M., Butenhoff, J.L., Mandel, J.H., and Zobel, L.R.
2004. Quantitative evaluation of perfluorooctanesulfonate (PFOS) and other fluorochemicals in the
serum of children. J. Children's Health 2:1-24; Kannan, K., Corsolini, S., Falandysz, J., Fillmann, G.,
Kumar, K.S., Loganathan, B.G., Mohd, M.A., Olivero, J., Van Wouwe, N., Yang, J.H., and Aldoust,
K.M. 2004. Perfluorooctanesulfonate and related fluorochemicals in human blood from several
countries. Environ. Sci. Technol. 38(17): 4489-95.

29 ¹² Olsen, G.W., Burris, J.M., Lundberg, J.K., Hansen, K.J., Mandel, J.H., and Zobel, L.R. 2002.
30 Identification of Fluorochemicals in Human Sera: III. Pediatric Participants in a Group A Streptococci
31 Clinical Trial Investigation (3M Company, Medical Department, Epidemiology, St. Paul, MN), U.S.
32 EPA Public Docket AR-226-1085.

33 ¹³ Olsen (2003) Environ. Health Perspect. 111:1892-1901; Olsen (2002).

12. The bio-accumulation of PFOA is a very serious concern in light of the body of evidence that demonstrates that PFOA causes cancer. Multiple studies have documented that PFOA causes liver, pancreatic, and Leydig cell (testicular) cancer in animals.

In one study, groups of rats were fed diets containing 0, 30, or 300 ppm of a PFOA salt (APFO) for two years, with an average consumption per day of 14.2 mg/kg-day for male rats and 16.1 mg/kg-day for female rats.¹⁴ Postmortem studies were conducted on all rats that died throughout the study, as well as on a group selected at the one year interim, and all remaining rats at the two-year termination of the experiment. The study found a statistically significant, dose-related increase in Leydig cell adenomas in male rats (4% and 14% in the low- and high-dose groups, compared to 0% in the control group and .82% in historical controls). This study also found an increase in the incidence of mammary fibroadenomas in female rats (at a rate of 43% in the high-dose group, compared to 21% in the control).¹⁵

That PFOA causes Leydig-cell tumors was confirmed in a later study of PFOA toxicity in male rats.¹⁶ This study fed PFOA to the animals by gavage at 300 ppm for 2 years, and analyzed the animals at 1, 3, 6, 9, 12, 15, 18, and 21 months. The scientists found a statistically significant increase in Leydig-cell tumors in the treated rats (11%, compared to 0% in the control group).

¹⁴ Sibinski, L. J. 1987. Two-Year oral (diet) toxicity/carcinogenicity study of fluorochemical FC-143 (perfluorooctane ammonium carboxylate) in rats. Riker Laboratories, Inc., Experiment No. 0281CR0012, available at U.S. EPA Public Docket AR-226-0437.

¹⁵ According to the EPA, this study improperly concluded that the increased rates of mammary fibroadenomas were not statistically significant, based on an improper historical control rate from an earlier study. U.S. EPA, Draft Risk Assessment of the Potential Human Health Effects Associated With Exposure to Perfluorooctanoic Acid And Its Salts, Office of Pollution Prevention and Toxics, Risk Assessment Division (January 4, 2005), at 57. The EPA report concludes that the increase shown in the study is statistically significant when compared to the historical control incidence for mammary fibroadenomas of 19% that has been used in 17 carcinogenicity studies. *Id.*

¹⁶ Biegel, L. B., Hurtt, M. E., Frame, S. R., O'Connor, J. C. and Cook, J. C. 2001. Mechanisms of Extrahepatic Tumor Induction by Peroxisome Proliferators in Male CD Rats. *Toxicol. Sci.* 60: 44-55; Cook, J.C., Hurtt, M.E., Frame, S.R., and Biegel, L.B. 1994. Mechanisms of extrahepatic tumor induction by peroxisome proliferators in Crl:CD BR (CD) rats. *Toxicologist* 14:301 (abstract #1169).

1 • The second study found liver and pancreatic tumors as well. The treated rats exhibited
2 significantly increased hepatic β -oxidation activity and increased incidence of
3 hepatocellular adenomas (at a rate of 13%, compared to 3% in the control group). The
4 study also found a statistically significant incidence of pancreatic acinar-cell adenomas
5 and carcinomas (at a rate of 11%, compared to the control rate of 0%).

6 • Other studies have also demonstrated that PFOA acts as a promoter of liver tumors in rats
7 when combined with other cancer initiators.¹⁷

8 13. In sum, PFOA meets the requirement for listing as a chemical causing cancer under the
9 standard set forth in 22 C.C.R. §12306(e)(2).

10 14. Unlike many chemicals that come before the CIC, the vast majority of California residents
11 likely have been exposed to this chemical, and actually have some amount of this chemical in their
12 blood. The widespread and continuing exposure of Californians to this hazardous chemical warrants an
13 abbreviation of the typical prioritization procedures to protect the public health. The CIC should
14 therefore place PFOA on the agenda of the next scheduled meeting, according to the abbreviated listing
15 procedure described in OEHHA, Process For Prioritizing Chemicals For Consideration Under
16 Proposition 65 By The "State's Qualified Experts," December 2004. Given the potential severity of the
17 health hazards caused by PFOA and the nearly universal exposure of the public, the CIC should list
18 PFOA under Proposition 65 as soon as possible.

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27 ¹⁷ Abdellatif, A.G., Preat, V., Taper, H.S., and Roberfroid, M. 1991. The modulation of rat liver
28 carcinogenesis by perfluorooctanoic acid, a peroxisome proliferator. Toxicology and Applied
 Pharmacology. 111(3): 530-7; Nilsson, R., Beije, B., Preat, V., Erxson, K., and Ramel, C. 1991. On the
 mechanism of the hepatocarcinogenicity of peroxisome proliferators. Chem. Biol. Interact. 78: 235-250.

CONCLUSION

For the reasons stated above, the CIC should consider PFOA at its next scheduled meeting and list PFOA under Proposition 65.


Dated: February 22, 2006

Respectfully submitted,

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